

Notice of Allowability

Application No.

10/663,454

Examiner

Joanne Hama, Ph.D.

Applicant(s)

MURRAY ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/15/07.
2. ☒ The allowed claim(s) is/are 1, 3, 13-15, 20, 21, 33, 35, 36 and 38-43.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Paula Borden on March 27, 2007.

The application has been amended as follows:

Claim 1 has been rewritten as follows:

A non-human transgenic mammal whose genome comprises a transgene comprising a nucleotide sequence encoding a stearoyl coenzyme A desaturase, wherein said desaturase-encoding nucleotide sequence is operably linked to a mammary gland-specific promoter, wherein the transgene is expressed in a mammary gland epithelial cell of said mammal, and wherein said mammal produces milk comprising a level of monounsaturated fatty acids (MUFA) that is at least 5% higher than the level of MUFA in milk produced by a non-transgenic mammal of the same species.

Claim 13 has been rewritten as follows:

A method for producing a non-human transgenic mammal of claim 1, said method comprising :

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a) introducing a transgene construct into a single-celled embryo, forming a genetically modified embryo, wherein said transgene construct comprises a nucleotide sequence encoding a stearyl coenzyme A desaturase (SCD), and wherein said SCD-encoding nucleotide sequence is operably linked to a mammary gland-specific promoter;

b) transferring the genetically modified embryo into a recipient pseudopregnant female of the same species;

c) allowing said transferred embryo to develop to term; and

d) identifying a transgenic non-human mammal whose genome comprises the transgene construct, wherein said transgenic non-human mammal produces milk comprising a level of monounsaturated fatty acids (MUFA) that is at least 5% higher than the level of MUFA in milk produced by a non-transgenic mammal of the same species.

The following is an examiner's statement of reasons for allowance:

With regard to the breadth the "non-human transgenic mammals" being claimed, the Examiner has determined that the instant invention is similar to that of a bioreactor. That is, a protein of interest is expressed in milk. As such, the claims have support for this breadth.

With regard to the breadth of stearyl coenzyme A desaturase (SCD) being obtainable from any species of animal, the art teaches that the structure/function of the enzyme was well known at the time of filing. Further, it is noted that the unpredictability

of a heterologous protein's biological activity in a transgenic animal is not an issue here as SCD's substrate is not another protein, but a fatty acid. For further discussion, see Office Action, December 15, 2006, pages 2-3.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your

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JH

ANNE M. WEHBE PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'AMW', written over the printed name of the examiner.